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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,997	04/24/2000	Ganesh Venkataraman	M0656/7055 (HCL)	7686

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WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/557,997

Applicant(s)

VENKATARAMAN ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,37 and 54-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37 and 54-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10052006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendments and remarks, filed 9/8/06, are acknowledged. Amended claim 36 and new claim 73 are acknowledged.

Applicant's arguments, filed 9/8/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The information disclosure statement, filed 10/5/06, has been considered by the Examiner. It is noted that van Kuik et al. references (C200 and C201) have been crossed out as they have already been considered in a previous PTO-892 form, mailed 3/2/06.

Claims 36-37 and 54-73 are herein under examination.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-37 and 54-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

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Claim 36 (line 9) recites the limitation “the identifier” which lacks clear antecedent basis. It is unclear if “the identifier” is referring to the identifier of the first data structure (line 4) or the identifier of the second data structure (line 7) or both. Clarification of this issue via clearer claim wording is requested. Claims 37 and 54-72 are also rejected due to their dependency from claim 36. This rejection is necessitated by amendment.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-37, 54-64, and 66-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Kuik et al. (Carbohydrate Research, Volume 235, 1992, pages 53-68) in

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view of Bohne et al. (Journal of Molecular Modeling, Volume 4, 1998, pages 33-43). This rejection is necessitated by amendment.

Van Kuik et al. describe a method for determining partial and complete matches between the carbohydrate structures of a query sequence and a polysaccharide via a database computer program (abstract) including monosaccharides and lactose-type chain (i.e. of disaccharide with Gal-Glc sequence) (page 54, third and last paragraph), as stated in instant claims 36, 59, and 60. Van Kuik et al. describe the database program runs on IBM compatible personal computers using MS-DOS (page 54, third paragraph). Table I shows a database record in ASCII format comprising a sequence listing with an identifier (H#) and various fields of value information including PPM values. Table II (A) shows a query sequence listing with a first data structure in the input screen of the program including an identifier (i.e. N on line 3) in a field with PPM values for the query sequence which represents a first data structure tangibly embodied in a computer readable medium. Table II (B) shows the program's output screen of a polysaccharide, which is not a nucleic acid, represented by a second data structure tangibly embodied on a computer readable medium including an identifier (S#: N-0A02-003860) that includes fields storing values (i.e. PPM values) for the monosaccharide residues, as stated in instant claim 36. Van Kuik et al. describe searching the database for structure matches with a user-defined profile of structures (page 57, first paragraph) as well as the "Start Search" button on the Input screen (Table II (A)) which represents a user providing input for one or more fields of the first data structure with an input device, as stated in step (A) of instant claim 36. Van Kuik et al. describe adding residue constraints to the search profile as well as searching and counting only relevant residues inside a tolerance limit (page 55, last line and page 57, lines 1-5) which represents

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generating at least one mask with the values stored in one or more fields of the first data structure, as stated in step (B) of instant claim 36. Van Kuik et al. describe using “AND”, “OR”, or “NOT” operations with the hit lists wherein the hit list search took place within the tolerance limit, combining searches (page 57, first paragraph), as well as using “N”s on hit structures (Table IV) and output results (Table II(B) and Table IV) which represent performing at least one binary operation, such as “AND”, on the values stored in the one or more fields of the second data structure using at least one mask to generate at least one result (as stated in instant claims 36 and 71) as well as combining results with an “OR” operation to generate at least one result (as stated in instant claim 72). Van Kuik et al. describe results with matching structural elements highlighted (abstract, Tables II (B) and IV) which represents determining whether the monosaccharides or dissacharides of the query sequence match the monosaccharides or dissacharides of the polysaccharide with at least one result, as stated in step (D) of instant claim 36. Van Kuik et al. describe the program and database require 3.5 Mbytes of disc space and Table II shows fields of data structures wherein each field represents a bit (unit of information storage) field, as stated in instant claim 37. Table II shows numerical PPM values which represent non-character based fields, as stated in instant claim 54. Van Kuik et al. describe a query sequence as “Structure I” (page 62) and a polysaccharide result example as “N-0A02-003860” (Table II (B)) which represent numerical identifiers, as stated in instant claim 55. Van Kuik et al. describe the monosaccharides of the query sequence (page 62) and polysaccharide sequence (Table IV) from numbers 1 to 8 which identify the constituents in the carbohydrate chains (Figure 2 caption, page 62) which represent single digit hexadecimal identifier numbers, as stated in instant claim 56. Table II lists PPM values with decimal values and Table IV lists

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fraction codes which represent decimal value identifiers which may be reduced to a plurality of prime divisors (i.e. one and three for N2.1 of page 64), as stated in instant claims 57 and 58. Van Kuik et al. describe PPM values of the monosaccharides in the polysaccharide sequence (Table II) which represent NMR properties of the monosaccharides in the polysaccharide sequence, as stated in instant claim 61. Tables II (B) shows the identity of the polysaccharide as well as its monosaccharides and their associated PPM values which represent the identity and exact chemical structure of the polysaccharide, as stated in instant claims 62, 63, and 68. Van Kuik et al. describe fraction N2 contained compounds with two negative charges (page 59, first paragraph) which represent properties comprising the charge, as stated in instant claim 64. Van Kuik et al. describe preparing oligosaccharides involving sulfosalicylic acid, 1% sodium dodecyl sulfate, and 73 U of peptide-N-(N-acetyl- β -D-glucosaminyl)-asparagine amidase F which represents properties comprising the nature and degree of sulfation and acetylation (page 57, second paragraph), as stated in instant claims 66 and 67. Van Kuik et al. describe percent match results of the hit structures (polysaccharides) with the query sequence (Table IV, column 6 from left) which represents the act of determining step with a result that has a non-zero value, as stated in instant claim 69. Table I contains PPM values for GlcNAc (acetylglucosamine) which is a monosaccharide of a heparin-like glycosaminoglycan, as stated in instant claim 70. Van Kuik et al. describe analyzing carbohydrate fractions prepared from a pool of horse serum glycoproteins (abstract and page 57, second paragraph). Van Kuik et al. do not describe an identifier includes a value for a disaccharide of the polysaccharide.

Bohne et al. describe a software tool SWEET for analyzing sequence information of complex carbohydrates (abstract). Bohne et al. describe inputting disaccharide strings (page 35,

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col. 2, last paragraph), obtaining values of each disaccharide, including Gal β (1-2)Gal β , (Figures 4a and 4b and their captions; page 38, last paragraph of col. 1 to first paragraph of col. 2), comparing (matching) query disaccharides with reference disaccharides (Table 1 with identifiers including values and page 42, col. 1, last paragraph), and output modes (Figure 7 and page 40, Output section) including a user generating sequence information and results sent back via email (page 42, col. 1, third paragraph). Bohne et al. describe using databases (page 42, col. 2, second paragraph) and data collections where the sequence of complex carbohydrates is stored, including CarbBank which contains sequences of all types of saccharides (page 34, col. 1, first paragraph). Bohne et al. describe values in Table I of disaccharides containing GalNAc and GlcNAc which represent a monosaccharide of a heparin-like glycosaminoglycan, as stated in instant claim 70.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the carbohydrate structure matching method of van Kuik et al. with the program SWEET involving disaccharide subunits of Bohne et al. where the motivation would have been to assist all glycoscientists dealing with structural and conformational aspects of oligo- and polysaccharides via easy accessible and searchable interfaces, as taught by Bohne et al. (page 42, col. 2, third paragraph and page 35, col. 1, second paragraph). One would have expected success in combining these limitations as Bohne et al. state that SWEET can visualize and analyze structures and then submit them to other more comprehensive computational methods as it can be accessed worldwide by a standard interface using many different hardware platforms (page 42, col. 2, third paragraph).

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Thus, van Kuik et al. in view of Bohne et al. make obvious claims 36-37, 54-64, and 66-73.

Applicants argue that van Kuik et al. do describe identifiers can be represented as a single digit hexadecimal number. This statement is found unpersuasive as numbers 1 to 8 recited in Figure 2 are single digits which encompass the representation of single digit hexadecimal numbers, since the hexadecimal number system that contains 16 unique symbols including numbers 0 to 9 and letters A to F. Applicants argue that van Kuik et al. do not teach comparing monosaccharides or disaccharides with values representing a property comprising charge. This statement is unpersuasive as the claims do not specifically recite such a limitation. It is noted that van Kuik et al. describe adding constraints to the search profile including binary operations (i.e. AND) (page 57, first paragraph) as well as noting compounds containing negative charges and mL values (page 59, first paragraph and Figure 1) which broadly and reasonably represents a value corresponding to the negative charges. Applicants summarize part of van Kuik et al. regarding preparing oligosaccharides with a certain enzyme which represents properties comprising nature and degree of sulfation and acetylation and argue that van Kuik et al. merely disclose how oligosaccharides were obtained on page 57, second paragraph. This statement is found unpersuasive as page 57 recites a "correspondence" to the nature and degree of sulfation and acetylation as broadly and reasonably interpreted in the broad claim language in recited in claim 61 from which claims 66 and 67 depend. Applicants argue that van Kuik et al.'s recitation of horse serum glycoproteins merely indicates that there were glycoproteins in the fractions but not necessarily heparin-like glycosaminoglycans. This statement is found unpersuasive as the

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claim does not require that heparin-like glycosaminoglycan, but rather a monosaccharide or disaccharide of a heparin-like glycosaminoglycan. Table I contains PPM values for GlcNAc (acetylglucosamine) which is a monosaccharide of a heparin-like glycosaminoglycan.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Kuik et al. (Carbohydrate Research, Volume 235, 1992, pages 53-68) and Bohne et al. (Journal of Molecular Modeling, Volume 4, 1998, pages 33-43) as applied to claims 36-37, 54-64, and 66-

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73 above, and further in view of Van Kuik et al. (Trends in Biotechnology, Volume 10, 1992, pages 182-185). This rejection is necessitated by amendment.

Van Kuik et al. (A) (1992, Carbohydrate Research) and Bohne et al. describe the limitations of claims 36-37, 54-64, and 66-73 (see above). Van Kuik et al. (A) (1992, Carbohydrate Research) and Bohne et al. do not describe properties comprising the molecular weight of the monosaccharide or disaccharide of the polysaccharide (instant claim 65).

Van Kuik et al. (B) (1992, Trends in Biotechnology) describe using databases of complex carbohydrates to search for carbohydrate structures (title and page 183, col. 1, third paragraph). Van Kuik et al. (B) describe searching monosaccharides and all residues attached to it (page 183, col. 1, fourth paragraph) which encompasses the search of monosaccharides, disaccharides, and other oligosaccharides. Van Kuik et al. (B) describe searches can be made for other items including molecular formula and molecular weight (page 183, col. 2, first paragraph) which represents properties comprising molecular weight, as stated in instant claim 65.

Van Kuik et al. (B) state review articles provide easy access to data but cover only selected parts of NMR data which is neither corrected or updated which is why it is a good idea to store NMR tables in a computer database and develop a program for easy manipulation of the data (page 184, col. 2, second paragraph). Van Kuik et al. (B) state as the number of published tables grows exponentially, a computerized approach of data storage and retrieval is essential (page 185, col. 1, fourth paragraph). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the carbohydrate structure matching method of van Kuik et al. with the program SWEET involving disaccharide subunits of Bohne et al. where the motivation would have been to assist all glycoscientists dealing with structural and

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conformational aspects of oligo- and polysaccharides via easy accessible and searchable interfaces, as taught by Bohne et al. (page 42, col. 2, third paragraph and page 35, col. 1, second paragraph). One would have expected success in combining these limitations as Bohne et al. state that SWEET can visualize and analyze structures and then submit them to other more comprehensive computational methods as it can be accessed worldwide by a standard interface using many different hardware platforms (page 42, col. 2, third paragraph). It would have been further obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of van Kuik et al. and Bohne et al. via searching other items, such as molecular weight, as stated by Van Kuik et al. (B) (page 183, col. 2, first paragraph) along with structure search of carbohydrates, as stated by Van Kuik et al. (A) (abstract) and (B) (page 183, col. 1, last paragraph) in order to narrow the search as stated by Van Kuik et al. (B) (page 183, col. 1, last paragraph). The person of ordinary skill in the art would have been motivated to make this modification because the CCSD database is growing rapidly and if the hits are too large to browse through, then supplementary searches can be made to narrow the number of branches or monosaccharide residues or put other constraints by using different search profiles, as stated by Van Kuik et al. (B) (page 183, col. 1, last paragraph and col. 2, third paragraph). One would have expected success in combining these limitations as both van Kuik et al. references deal with the same database program involving ^1H NMR (Van Kuik et al. (A) abstract) and (B) (page 184, col. 2, second paragraph).

Thus, Van Kuik et al. (A) in view of Bohne et al. and Van Kuik et al. (B) make obvious the instant invention.

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Applicants argue that the previous 35 USC 103(a) rejection, mailed 3/2/06, is moot due to the amendment to claim 36. This statement is found unpersuasive as another reference has been applied to address this limitation. Applicants' arguments are deemed unpersuasive for the reasons given above.

The prior art "The Complex Carbohydrate Structure Database" (Doubet et al.) is made of record and not relied upon; however, it is considered pertinent to applicant's disclosure.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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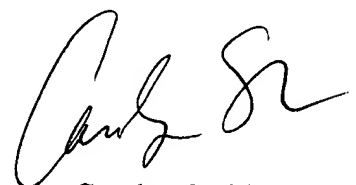
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

November 9, 2006

A handwritten signature in black ink, appearing to read 'Carolyn Smith', written in a cursive style.

Carolyn Smith
Examiner
AU 1631